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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,808	12/21/2001	Clas Kallander	KALL3001/REF	4746

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,808	KALLANDER ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 9-18* is/are pending in the application.

4a) Of the above claim(s) *16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 2, 2004 in response to the Office Action of October 1, 2003 is acknowledged and has been entered. Claims 12-18 have been added. Claims 1-4 and 9-15 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Newly submitted claims 16-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of claims 1-4, 13-15 and claims 16-18 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In this instnace prA coated plated can be made using a materially different coupling agent, therefore the product as claimed can be made by a materially different process that results in the same structure.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The rejection claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite **is withdrawn** in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 9, 10, 12 and newly added claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al. (Antiviral Chemistry and Chemotherapy, 1997; see IDS) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicant reminds the Office that the reply to the arguments must be address all arguments presented citing MPEP 2113, 2131, 2143 and 2144 in response. Applicant's arguments are (1) that each and every element set forth in claim must be either expressly or inherently described in a single prior art reference, (2) that the innovation for the production of the prA coated microtiter plate are not expressly described in the prior art references, (3) the current invention provided the innovation for the application of this technique for commercial production of RT activity kits. (4) the new procedure according to the invention provides a simple, non-toxic, inexpensive method to manufacture large batches of prA coated microtiter plates. The new plates are stable during storage, give minimal variation and can be delivered ready to use. It is important to note that the claims are drawn to a product-by-process wherein the process step comprises methylimidazole, as written the claims do not exclude the use of other components in the reaction mixture.

Applicant's arguments (points 1-4 above) are that the method of attaching the prA to plate differs from the methods used in the prior art. The original claims, however, are not directed to a method of attaching prA to the polystyrene plates, instant claims are drawn to a composition. The claims are directed to a product (composition) and a method of using the product. The process steps for obtaining the product will not be given weight unless the process steps result in a different structure. Applicants have not provided any objective evidence

indicating that the prA linked to the polystyrene plate of the instant invention is structurally different than the prA bound to the polystyrene plates of the prior art. Applicant's have not provided any evidence showing that this structural difference is due to the different chemistry that couples the polynucleotide to the plate. Therefore, Applicant's argument that the instant invention has feature such as being non-toxic, inexpensive and more stable does not address any differences in the structure. Applicant's arguments have focused on the different methods of attaching the prA to the solid phase. Applicants argue that cited reference does not set out the specific steps for attaching the prA to the plates. This is not found persuasive as the Ekstrand et al. references cited by the Shao et al. reference indicates that standard chemicals for the covalent coupling of the prA to the Covalink plates was used. The Covalink instructions (provided by the manufacturer) recommend a carbodiimide and methylimidazole combination for attaching polynucleotides to the plates (see manufacturers instructions attached to the instant Office action).

> While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus [in this case a polystyrene plate] must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)
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> "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.).

The instant invention is drawn to a kit comprising: (1) prA bound to polystyrene plate; (2) RT-type assay components (a) buffer pH7-8, (b) divalent metal ion, (c) chelator, (d) polyamnine, (e) RNAse inhibitor, (f) reducing agent, (g) salt, (h) stabilizing agent.(i) detergent, (j) deoxynucleotide triphosphate, (k) primer, (l) protective agent, (m) washing buffer; (3) The kit may also contain (but does not require) a reference enzyme and a detection system. The invention includes a method of using the kit for the analysis of RT activity in a biological sample.

For this office action, the product-by-process claims were interpreted as "a composition of matter" (which are *products*, wherein the chemical nature (prA or pdA bound to a solid surface) or materials used. Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps (M.P.E.P. Section 2113).

Shao et al. disclose the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see figure 1). In the materials and methods (see page 150, column 2, 1st paragraph). "The performance and the principle of the kit assay based on colorimetric detection of RT activity product, were recently described in detail (Ekstrand et al. 1996). The prototype consist of (i) template, i.e. 96-well microtiter plate with prA bound to the bottom of the wells [the Ekstrand et al. 1996 cited by Shao et. al used a Covalink plate] (ii) an RT reaction reconstitution buffer, (iii) separately lyophilized primer (iv) a dilution buffer for RT and substances to be analyzed (v) a concentrated plate wash buffer". Therefore, the instant invention is anticipated Shao et al.

Claims 1, 4, 9-12 and newly added claim 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekstand et al. (Biotechnology Applied Biochemistry, 1996; see IDS) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicant's arguments are (1) that each and every element set forth in claim must be either expressly or inherently described in a single prior art reference, (2) that the innovation for the production of the prA coated microtiter plate are not expressly described in the prior art references, (3) the current invention provided the innovation for the application of this technique for commercial production of RT activity kits. (4) the new procedure according to the invention provides a simple, non-toxic, inexpensive method to manufacture large batches of prA coated microtiter plates. The new plates are stable during storage, give minimal variation and can be delivered ready to use. It is important to note that the claims are drawn to a product-by-process wherein the process step comprises methylimidazole, as written the claims do not exclude the use of other components in the reaction mixture.

Applicant's arguments (points 1-4 above) are that the method of attaching the prA to plate differs from the methods used in the prior art. The original claims, however, are not directed to a method of attaching prA to the polystyrene plates, instant claims are drawn to a composition. The claims are directed to a product (composition) and a method of using the product. The process steps for obtaining the product will not be given weight unless the process steps result in a different structure. Applicants have not provided any objective evidence indicating that the resulting prA linked to the polystyrene plate is structurally different than the prA bound to the polystyrene plates of the prior art and that this structural difference is not due to

the particular polystyrene plate used but is because of the different chemistry that couples the polynucleotide to the plate. Therefore, Applicant's argument that the instant invention has features such as being non-toxic, inexpensive and more stable does not address any differences in the structure. Applicant's arguments have focused on the different methods of attaching the prA to the solid phase. Applicants argue that cited reference does not set out the specific steps for attaching the prA to the plates. This is not found persuasive as the Ekstrand et al. indicates the use of standard chemicals for the covalent coupling of the prA to the Covalink plates. The Covalink instructions (proved by the manufacturer) recommend a carbodiimide and methylimidazole combination for attaching polynucleotides to the plates (see manufacturers instructions attached to this office action).

> While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus [in this case a polystyrene plate] must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)
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The instant invention is drawn to a kit comprising: (1) prA bound to polystyrene plate; (2) RT-type assay components (a) buffer pH7-8, (b) divalent metal ion, (c) chelator, (d) polyamnine, (e) RNAse inhibitor, (f) reducing agent, (g) salt, (h) stabilizing agent. (i) detergent,

(j) deoxynucleotide triphosphate, (k) primer, (l) protective agent, (m) washing buffer; (3) The kit may also contain (but does not require) a reference enzyme and a detection system. The invention include a method of using the kit for the analysis of RT activity in a biological sample.

For this office action, the product-by-process claims were interpreted as "a composition of matter" (which are *products*, wherein the chemical nature (prA or pdA bound to a solid surface) or materials used. Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps (M.P.E.P. Section 2113).

Ekstand et al. disclose the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see page 97, template binding and enzyme assay). The reference discloses using Covalink plates with the standard covalent coupling reagents (see page 96, column 2, 1st paragraph), the manufacturers suggest carbodiimide and methylimidazole combination for coupling polynucleotides to the plates. There is nothing in the reference that would indicate Ekstand et al. did not use the manufacturers suggested coupling procedure. The instant reference discloses an RT assay using (a) HEPES buffer pH 7.6, (b) MgCl2, (c) EGTA, (d) spermine, (e) dextran sulfate, (f) mercaptoethanol, (g) KCL, (h) BSA, (i) Triton-X 100, (j) BrdUTP, (k) primer, (l) deoxynucleotride triphosphate, (m) washing buffer (see page 97, enzyme assay). Therefore, the instant invention is anticipated by Ekstand et al.

Claim Rejetions - 35 USC § 103

Claims 1-4, 9-12 and newly added claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shao et al. (Antiviral Chemistry and Chemotherapy, 1997; see IDS),

Ekstand et al. (Biotechnology Applied Biochemistry, 1996; see IDS), Suzuki et al. (Journal of Virological Methods, 1993) and Rasmussen et al. (Analytical Biochemistry, 1991 **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicant's arguments are (1) that each and every element set forth in claim must be either expressly or inherently described in a single prior art reference, (2) that the innovation for the production of the prA coated microtiter plate are not expressly described in the prior art references, (3) the current invention provided the innovation for the application of this technique for commercial production of RT activity kits. (4) the new procedure according to the invention provides a simple, non-toxic, inexpensive method to manufacture large batches of prA coated microtiter plates. The new plates are stable during storage, give minimal variation and can be delivered ready to use. It is important to note that the claims are drawn to a product-by-process wherein the process step comprises methylimidazole, as written the claims do not exclude the use of other components in the reaction mixture.

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evidence showing that this structural difference is due to the different chemistry that couples the polynucleotide to the plate. Therefore, Applicant's argument that the instant invention has feature such as being non-toxic, inexpensive and more stable does not address any differences in the structure. Applicant's arguments have focused on the different methods of attaching the prA to the solid phase. Applicants argue that cited references do not set out the specific steps for attaching the prA to the plates. This is not found persuasive as the Ekstrand et al. references cited by the Shao et al. reference indicates that standard chemicals for the covalent coupling of the prA to the Covalink plates was used. The Covalink instructions (provided by the manufacturer) recommend a carbodiimide and methylimidazole combination for attaching polynucleotides to the plates (see manufacturers instructions attached to this office action).

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(j) deoxynucleotide triphosphate, (k) primer, (l) protective agent, (m) washing buffer; (3) The kit may also contain (butdoes not require) a reference enzyme and a detection system. The invention includes a method of using the kit for the analysis of RT activity in a biological sample.

Shao et al. teaches the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see figure 1). In the materials and methods (see page 150, column 2, 1st paragraph). "The performance and the principle of the kit assay based on colorimetric detection of RT activity product, were previously described (Ekstrand et al. 1996). The prototype consist of (i) template, i.e. 96-well microtiter plate with prA bound to the bottom of the wells [the Ekstrand et al. 1996 cited by Shao et. al used a Covalink plate] (ii) an RT reaction reconstitution buffer, (iii) separately lyophilized primer (iv) a dilution buffer for RT and substances to be analyzed (v) a concentrated plate wash buffer".

Ekstand et al. teaches the use of a non-radioactive microtiter plate RT-assay in which the immobilized template polyriboadenylic acid (prA) is bound to the plate (see page 97, template binding and enzyme assay). The reference discloses using the Covalink plates with the standard covalent coupling reagents (see page 96, column 2, 1st paragraph), the manufacturers suggest carbodiimide and methylimidazole combination for coupling polynucleotides to the plates. There is nothing in the reference that would indicate Ekstand et al. did not use the manufacturers suggested coupling procedure. The instant reference discloses an RT assay using (a) HEPES buffer pH 7.6, (b) MgCl2, (c) EGTA, (d) spermine, (e) dextran sulfate, (f) mercaptoethanol, (g)

KCL, (h) BSA, (i) Triton-X 100, (j) BrdUTP, (k) primer, (l) deoxynucleotride triphosphate, (m) washing buffer (see page 97, enzyme assay).

Suzuki et al. teaches an RT assay in which the poly A was linked to microtiter plates using hydroxysulfosuccinimide and 1-ethyl-3-(3-hydroxysulfosuccinimide) carboiimide hydrochloride. The reference teaches an RT assay using biotin-dUTP solution, TTP, KCL, Mg2Cl, Tris, pH 7.8, DTT oligo dT for the RT reaction. The HRP enzyme reaction was carried using TMB as the final color reactant (see page 191). The reference does not teach the use of an RNA inhibitor, a polyamine, a stabilizing agent or the use of protective agents in the RT assay buffer.

Rasmussen et al. teaches the covalent immobilization of double stranded and single stranded DNA to polystyrene microwells on a CovaLink NH plate. The reference utilizes 10 mM 1-methylimidazole in the binding buffer and an incubation temperature of 50C for 5 hours (this is the same reaction mixture as the one suggest by the manufacturer of Covalink plates) The reference also teaches using various concentrations of EDC and 1-methylimidazole (see page 140, column1 2nd paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the binding condition for the poly A or poly dA to the polystyrene based ELISA plate to obtain the maximum signal from the RT assay as set out in Shao et al. and Ekstand et al. Suzuki et al. utilizes Covalink plates from NUNC and the coupling agent EDC [1-ethy-3-(3-dimethylaminopropyl)-carboiimide] in N-hydroxysulfosuccinimide to bind the poly A to the bottom of the plate. Rasmussen et al. utilizes the CovaLink NH plates in conjunction with the coupling agent EDC dissolved in 1-methylimidazole. Single stranded DNA has the similar

structure to poly dA and poly A, therefore, one of ordinary skill in the art would have had a high expectation of success in applying the EDC coupling agent in 1-methylimidazole for the efficient directional binding to the bottom of the plate as taught by Rasmussen et al. The reference also uses the same carbodiimide condensing agent as suggests by the manufacturer of the CovaLink NH plates. Optimizing the conditions such as varying the 1-methylimidazole and condensing agent for binding the target onto the bottom of the plate would fall within the skill of the ordinary artisan and is suggest by Rasmussen et al. Therefore, based on what was known in the art the instant assay kit and methods are obvious over Shao et al., Ekstand et al., Suzuki et al. and Rasmussen et al.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 4/30/04